REMARKS

The examiner has issued a restriction requirement under 35 USC §121 and §372. Applicants provisionally elect Group I, claims 1-6, and respectfully traverse this restriction requirement. It is submitted that claims 1-7 comply with PCT Rule 13 Unity of Invention requirements, and therefore with 37 CFR §1.475(a), in that these claims share a common technical feature that defines them collectively over the prior art. Applicants accordingly request that the restriction requirement of record be withdrawn.

According to 37 CFR §1.475, and PCT Rule 13, the claims of an application must contain a special technical feature that defines them collectively over the prior art. This demonstrates a common technical relationship between the claims, and shows that they form a single inventive concept. Once this single inventive concept has been established, a finding of unity of invention is proper.

The examiner asserts that Group I (claims 1-6) and Group II (claim 7) are "not so linked ... as to form a single inventive concept," and that "they do not share a common technical feature" (office action, p. 2). The examiner characterizes Group I claims as being "drawn to the use of TNF-antagonists ... for the treatment of sepsis disorders" (id.). Further, the examiner characterizes the Group II claim as being drawn to "steps to establish whether a sepsis patient is to be treated with TNF-antagonists" (id.). Applicants respectfully submit that this characterization of the claims does not accurately demonstrate the common special technical feature that defines the claims collectively over the prior art, and further, that such a feature does, in fact, exist between these claims.

To cite relevant language from the three independent claims directly (PCT Annex B, Part 1(c) indicates that unity of invention is to be determined among the independent claims), claim 1 defines

> [t]he use of TNF antagonists ... for treating *those septic disorders where the serum level of interleukin-6 increases in a measurement period of at least thirty minutes.* (emphasis added)

The next independent claim, claim 5, is to

> [a] commercial pack ... for treating *septic disorders where the serum level of IL-6 increases in a measurement period of at least thirty minutes.* (emphasis added)

Finally, claim 7 defines

> [a] method for establishing whether a patient suffering from *sepsis* is to be treated with TNF antagonists, which comprises ... *determination of [whether] the serum level of interleukin-6 in the patient [increases during an interval] which is at least 30 minutes after the first time [measurement].* (emphasis added)

As indicated in the specification, the present invention fills a need in the prior art to determine when treatment with TNF-antagonists is likely to be successful in patients having septic disorders (p. 2, lines 40-42). The success of such treatment has been determined to correlate with the relative increase of interleukin-6 in the patient's serum over a period of at least 30 minutes (p. 2, line 44 through p. 3, line 2). Applicants submit that this determination of an indicator for successful treatment of sepsis disorders is the special technical feature commonly held by claims 1-7. Each of claims 1, 5 and 7 contain this special technical feature.

Applicants submit that, as the present invention has been filed under the PCT, and as unity of invention can be demonstrated by this common technical relationship

defining a single inventive concept, the restriction requirement should be withdrawn. The claims of Group I and II have the same ultimate purpose, i.e., to successfully treat sepsis disorders using TNF-antagonists. That the Groups may require different searches is not relevant to the determination of unity under 37 CFR §1.475 and PCT Rule 13, where a common technical relationship defines them collectively over the prior art. Applicants therefore respectfully request reconsideration and withdrawal of the restriction requirement made under 35 USC §121 and §372.

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

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Respectfully submitted,
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